Amendments To The Claims

This listing will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (currently amended) A pharmaceutical composition comprising sodium 4-phenylbutyrate, ~~an effective amount of~~ at least one aromatic flavoring agent, and ~~an effective amount of~~ at least one synthetic sweetening agent comprising a mixture of aspartame and potassium acesulfame.

2. (original) A pharmaceutical composition according to claim 1, in which the aromatic flavoring agent is selected from fruit flavoring agents.

3. (original) A pharmaceutical composition according to claim 1, in which the aromatic flavoring agent is a strawberry flavoring agent.

4. (Cancelled)

5. (Cancelled)

6. (currently amended) A pharmaceutical composition according to claim 1, in which the sodium 4-phenylbutyrate is present in the form of granules which further comprise ~~an effective amount of~~ a binding agent.

7. (original) A pharmaceutical composition according to claim 6, which comprises, per 100 parts by dry weight of the composition;

from about 80 to about 90 parts by weight of sodium 4-phenylbutyrate;
from about 3.5 to about 5.0 parts by weight of aspartame;
from about 1.5 to about 3.5 parts by weight of potassium acesulfame;

from about 2.5 to about 5.0 parts by weight of an aromatic fruit flavoring agent; and
from about 3.5 to about 6.5 parts by weight of a binding agent.

8. (original) A pharmaceutical composition according to claim 7, in which the binding agent is polyvinylpyrrolidone.

9. (original) A pharmaceutical composition according to claim 7, in which the fruit flavoring agent is a strawberry flavoring agent.

10. (currently amended) A dry powder pharmaceutical composition comprising sodium 4-phenylbutyrate, ~~an effective amount of~~ at least one water soluble sweetening agent comprising a mixture of aspartame and potassium acesulfame, and ~~an effective amount of~~ at least one water soluble flavoring agent, the effective amounts being selected so as to mask substantially the bitter taste and pungent odor of sodium 4-phenylbutyrate.

11. (currently amended) A pharmaceutical composition which comprises granules comprising sodium 4-phenylbutyrate, a binding agent, ~~an effective amount of~~ at least one synthetic water soluble sweetening agent comprising a mixture of aspartame and potassium acesulfame, and ~~an effective amount of~~ at least one water soluble flavoring agent, the ~~effective~~ amounts being selected so that, upon dissolution in water to yield an aqueous solution that contains from about 10 to about 50 mg/ml of sodium 4-phenylbutyrate, the resulting aqueous solution is palatable.

12. (original) A pharmaceutical composition according to claim 11, which comprises per 100 parts by weight of the composition;
from about 80 to about 90 parts by weight of sodium 4-phenylbutyrate;
from about 3.5 to about 5.0 parts by weight of aspartame;
from about 1.5 to about 3.5 parts by weight of potassium acesulfame;
from about 2.5 to about 5.0 parts by weight of a strawberry flavoring agent; and
from about 3.5 to about 6.5 parts by weight of polyvinylpyrrolidone.

13. (currently amended) A concentrated aqueous solution containing at least about 200 mg/ml of sodium 4-phenylbutyrate up to the solubility limit thereof measured at 10°C, and having dissolved therein ~~an effective amount of~~ at least one water soluble sweetening agent comprising a mixture of aspartame and potassium acesulfame, and ~~an effective amount of~~ at least one water soluble flavoring agent, the effective amounts being selected so as to mask substantially, following dilution by at least about 5 fold up to about 10 fold or more with water, the bitter taste and pungent odor of sodium 4-phenylbutyrate.

14. (original) A concentrated aqueous solution according to claim 13, in which the flavoring agent is selected from fruit flavoring agents.

15. (original) A concentrated aqueous solution according to claim 13, in which the flavoring agent is a strawberry flavoring agent.

16. (Cancelled)

17. (Cancelled)

18. (original) A concentrated aqueous solution according to claim 13, which comprises, per 100 parts by weight of the dry components of the composition;

from about 80 to about 90 parts by weight of sodium 4-phenylbutyrate;
from about 3.5 to about 5.0 parts by weight of aspartame;
from about 1.5 to about 3.5 parts by weight of potassium acesulfame;
from about 2.5 to about 5.0 parts by weight of a fruit flavoring agent; and
from about 3.5 to about 6.5 parts by weight of polyvinylpyrrolidone.

19. (original) A concentrated aqueous solution according to claim 17, in which the fruit flavoring agent is a strawberry flavoring agent.

20. (currently amended) A unit dose for administration to a patient requiring treatment for a urea cycle deficiency according to a regime in which the patient is administered a predetermined number of doses daily corresponding to from about 450 to about 600 mg/kg/day of sodium 4-phenylbutyrate, the unit dose prepared by diluting with water an aliquot of a concentrated aqueous solution containing at least about 200 mg/ml of sodium 4-phenylbutyrate up to the solubility limit thereof measured at 10°C, ~~an effective amount of~~ at least one water soluble sweetening agent comprising a mixture of aspartame and potassium acesulfame, and ~~an effective amount of~~ at least one water soluble flavoring agent, the unit dose containing from about 10 to about 50 mg/ml of sodium 4-phenylbutyrate and the ~~effective~~ amounts being selected so as to mask substantially the bitter taste and pungent odor of sodium 4-phenylbutyrate.

21. (original) A unit dose according to claim 20, in which the amount of sodium 4-phenylbutyrate corresponds to no more than about one third of the maximum daily requirement of about 600 mg/kg/day.

22. (currently amended) A pharmaceutically acceptable aqueous solution ready for administration to a patient requiring treatment for a urea cycle deficiency according to a regime in which the patient is administered a predetermined number of doses daily corresponding to from about 450 to about 600 mg/kg/day of sodium 4-phenylbutyrate, the solution containing a unit dose of sodium 4-phenylbutyrate, an amount of at least one water soluble sweetening agent comprising a mixture of aspartame and potassium acesulfame, and an amount of at least one water soluble flavoring agent, the concentration of sodium 4-phenylbutyrate in the aqueous solution ranging from about 10 to about 50 mg/ml and the amounts of the at least one water soluble sweetening agent and of the at least one water soluble flavoring agent being selected so as to mask substantially the bitter taste and pungent odor of sodium 4-phenylbutyrate.

23. (currently amended) A pharmaceutical composition comprising granules comprising sodium 4-phenylbutyrate and a binding amount of a binding agent, the composition further

including ~~an effective amount of~~ at least one synthetic water soluble sweetening agent comprising a mixture of aspartame and potassium acesulfame, and ~~an effective amount of~~ the at least one water soluble flavoring agent, the amounts of at least one artificial water soluble sweetening agent and of the at least one water soluble flavoring agent ~~being sufficient~~ such that, upon dissolution in water ~~to~~ yield an aqueous solution containing from about 10 to about 50 mg/ml of sodium 4-phenylbutyrate to render the resulting aqueous solution palatable to a child.

24. (original) A pharmaceutical composition according to claim 23, in which the binding agent comprises polyvinylpyyrolidone.

25. (original) A pharmaceutical composition according to claim 23, in which the flavoring agent is selected from fruit flavoring agents.

26. (original) A pharmaceutical composition according to claim 25, in which the flavoring agent is a strawberry flavoring agent.

27. (Cancelled)

28. (Cancelled)

29. (original) A pharmaceutical composition according to claim 23, which comprises, per 100 parts by dry weight of the composition;

from about 82.5 to about 99.5 parts by weight of sodium 4-phenylbutyrate;

from about 3.25 to about 4.5 parts by weight of aspartame;

from about 1.75 to about 3.25 parts by weight of potassium acesulfame;

from about 3.25 to about 4.5 parts by weight of a water soluble fruit flavoring agent; and

from about 3.25 to about 5.25 parts by weight of polyvinylpyrrolidone.

30. (original) A pharmaceutical composition according to claim 29, in which the fruit flavoring agent is a strawberry flavoring agent.

31. (currently amended) A pharmaceutical composition according to claim 23, wherein the granules comprise sodium 4-phenylbutyrate and the binding agent and wherein the granules are mixed with the at least one synthetic water soluble ~~softening~~ sweetening agent and with the at least one water soluble flavoring agent to form the wetted mass.

32. (original) A pharmaceutical composition according to claim 23, wherein the granules comprise sodium 4-phenylbutyrate, the binding agent, the at least one synthetic water soluble sweetening agent and the at least one water soluble flavoring agent.

33. (**New**) A pharmaceutical composition comprising sodium 4-phenylbutyrate, at least one aromatic flavoring agent, and at least one synthetic sweetening agent comprising at least one synthetic sweetening agent selected from aspartame and potassium acesulfame.